

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO ETHICON WAVE 1 CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION
TO EXCLUDE THE TESTIMONY OF MICHAEL KARRAM, M.D. REGARDING THE
SAFETY AND EFFICACY OF THE TVT-O PRODUCT**

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") submit this response in opposition to Plaintiffs' motion to exclude the testimony of Michael Karram, M.D. regarding the safety and efficacy of the TVT-O product (Doc. 2091).

INTRODUCTION

Dr. Karram is a urogynecologist known nationally and internally in the field of gynecologic surgery and advanced pelvic surgery. Plaintiffs' Motion Ex. C, Karram Expert Report Doc. 2091-3 at 3. He has been board-certified in obstetrics and gynecology since 1986. Karram CV, attached hereto as Exhibit A. Dr. Karram has been in private practice with special interest in female pelvic medicine and reconstructive surgery, urogynecology, and minimally invasive surgery at the Seven Hills Women's Health Centers in Cincinnati, Ohio since 1984. *Id.* He is a member of the American Urogynecologic Society (AUGS), International Urogynecologic Association (IUGA), and the American Association of Gynecologic Laproscopists (AAGL), among other notable professional societies. *Id.* He has worked as a consultant, speaker, and advisor for many pharmaceutical companies, and specifically has worked for Ethicon as a

training instructor and preceptor, observing surgeons new to the procedure, with respect to Ethicon's TVT products. Expert Report at 2-3, 26.

Dr. Karram has performed incontinence surgeries since the beginning of his career and has employed a variety of surgical procedures, including native tissue and augmented repairs. Expert Report at 3. He began performing TVT surgeries in 1998 and has experience with retropubic, transobturator, and single incision slings. *Id.* Since 1998, he has performed over 2,000 sling operations, and it remains his preferred method of surgical correction of stress urinary incontinence. *Id.* at 4.

In these cases, Dr. Karram intends to offer opinions generally addressing the utility and safety of the various TVT devices, including TVT-O. His opinions are based upon his education, medical training, clinical experience, extensive review of medical literature, position statements, guidelines, practice patterns, curricula, and various other material reflected in his reliance list. Expert Report; Ex. B, Reliance List. He is qualified to opine on these topics and, as detailed below, his opinions are supported by reliable methodology.

Plaintiffs have challenged certain aspects of Dr. Karram's opinions, and as set forth below, Plaintiffs' arguments lack merit and should be denied.

ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D. W. Va. 2014).

I. Dr. Karram is qualified to render opinions regarding the utility and safety of the TVT-O device.

Dr. Karram has extensive experience and knowledge of the TVT products when clinically applied. He has performed over 2,000 sling operations in his career. Expert Report at 4. His reliance on this experience, knowledge, and consistent review of relevant literature in the daily

course of his practice qualify him as an expert on the safety and efficacy of the TVT-O and other TVT products.

Plaintiffs' attempt to support exclusion of Dr. Karram's testimony because he is not a published author in a peer-review journal is both simplistic and misguided. While peer-review is a factor that may bear on the reliability of expert testimony, it is not a requirement. *See Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001). In fact, in their Motion, the Plaintiffs' recognize that the short list of factors identified in *Daubert* are "neither definitive, nor exhaustive." Plaintiffs' Memo. in Supp., Doc. 2092 at 3 (quoting *Cooper*, 259 F.3d at 199); *see also United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

Plaintiffs point to a lack of published peer-reviewed writing on Dr. Karram's part, but offer no reason why this fact requires the disqualification of Dr. Karram. Though Dr. Karram has not been credited as an author specifically in any peer-review journals, Dr. Karram has published works, some of which are relied on and cited to by peer-reviewed publications. Plaintiffs' Motion Ex. B, Deposition of Dr. Karram, Doc. 2091-2 ("Karram Depo.") at 30:19 – 31:22.

Overlooking the fact that Dr. Karram is a highly qualified urogynecologist with extensive experience, Plaintiffs next cite a laundry list of areas where Dr. Karram admitted that he is not an expert. *See* Pltfs' Memo. at 4-5 (acknowledging no expertise in biomaterials, pathology, epidemiology, FDA regulations, drafting Instructions for Use materials, the development and design of medical devices, and statistics). But a lack of experience in these areas does not support exclusion of Dr. Karram's qualifications to opine regarding safety of TVT devices – as

Plaintiffs implicitly admit by failing to identify any of Dr. Karram's opinions that they believe should be excluded based on this alleged lack of expertise in these particular areas. They cannot.

As this Court has previously found, a urogynecologist's extensive experience with performing mesh implant and explant surgeries can qualify him to opine on "how the product reacts inside the body." *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 18872222 (S.D.W. Va. Apr. 24, 2015); *see also Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 585 (S.D. W. Va. 2014) (finding urogynecologist who has performed sling procedures over the last twenty years qualified to testify that mesh does not shrink, contract, degrade, or cause systemic infections); *Carlson v. Boston Scientific Corp.*, No. 2:13-cv-05475, 2015 WL 1931311 (Apr. 28, 2015) (finding physician's clinical experience and review of the scientific literature adequately qualified him to opine on polypropylene, including its degradation, leaching, shrinkage, and contraction); *Jones v. Bard, Inc.*, No. 2:11-cv-00114, at 6-9 (finding physician qualified to opine as to polypropylene and product design).

Like the physicians in those cases, Dr. Karram is a skilled urogynecologist with 18 years of experience in surgically treating urinary incontinence. Expert Report at 3. He has performed thousands of stress incontinence surgeries, using a variety of synthetic and biologic materials. *Id.* In choosing which procedures and products to use in his practice, he based his decision on review of clinical data and literature. Karram Depo. at 57:20-58:1. Both in the course of preparing his Report and as a regular part of his medical practice, he reviews textbooks, journal articles, abstracts, and other medical literature relevant to his practice. *See id.* at 95:2-7. His opinions are premised upon a thorough understanding of the interaction of the body with permanent surgical implants, along with clinical observations from performing thousands of mesh procedures, and regular and consistent review of relevant medical literature in the course of his practice and experience teaching and observing others learning to perform mesh surgeries.

Dr. Karram is an expert on many things. And without any direction provided by Plaintiffs as to which opinions they argue must be excluded, it is hard, if not impossible to more specifically reply to such accusations. Their vague attempt to exclude Dr. Karram's testimony on these grounds should be denied for this reason alone.

Moreover, some categories in which Plaintiffs suggest that Dr. Karram lacks expertise are irrelevant to his testimony. For example, although Dr. Karram's Report refers to statistical evidence, he is not providing his opinion on statistical methods but rather using the data to support his opinions on the safety and efficacy of the TVT products. To exclude all experts that refer to statistical evidence without being an expert in statistics is illogical and would result in the exclusion of most experts, and certainly many, if not most, of Plaintiffs' experts. Such a proposition is simply absurd. Dr. Karram is a highly qualified surgeon with years of experience with mesh devices, and is qualified to offer the opinions provided in his Report.

Nor is there any basis for excluding Dr. Karram's testimony based on Plaintiffs' suggestion that because Dr. Karram allegedly misrepresented his role in the Clinical Evaluation of Gynecare Thermachoice III Uterine Balloon System, he is somehow disqualified from proffering opinions on TVT devices. Plaintiffs' argument on this point makes no sense. Indeed, they fail to identify in any way how Dr. Karram's particular role in a study involving a non-TVT device is relevant to his qualifications regarding TVT or his methodology for forming his opinions. At most, this is an issue going to credibility and/or weight of testimony, not admissibility. As such, this argument is not appropriate for Plaintiffs' motion at hand. *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 596 (1993) ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attaching shaky but admissible evidence.").

Plaintiffs make much of the fact that Dr. Karram has not implanted the TVT-O device in the past five years – but offer no valid reason showing how the time between Dr. Karram’s last use of the product and his Report make his opinions or the data on which he relies unreliable. This is particularly true in the light of Dr. Karram’s explanation: He has not used TVT-O for the past five years simply because his hospital stocks Abbrevio and other similar products in lieu of TVT-O. Karram Depo. at 89:12-21. If his hospital can get TVT-O again, he will “probably start using it again.” *Id.* at 89:19-21. Furthermore, he has continued using other TVT devices made from the same PROLENE* material since he last implanted a TVT-O device. Dr. Karram has extensive clinical experience with the TVT-O devices – and the unavailability of TVT-O at his hospital has no bearing on the methodology used in forming his opinions and is no basis at all for excluding his testimony on this device. Dr. Karram is an expert in his field and has provided reliable opinions based on his experience and review of relevant data in this litigation. Plaintiffs’ motion should be denied.

II. Dr. Karram’s opinions are well supported by reliable methodology and are, therefore, admissible.

Dr. Karram has offered general opinions on the various TVT devices, employing sound methodology and using reliable data to support his opinions.

Plaintiffs suggest that Dr. Karram’s Report does not adequately addresses the TVT-O device – ignoring the fact that his Report addresses TVT devices generally. Dr. Karram’s references regarding the general safety and efficacy of “TVT” include the various TVT devices, including both TVT-O and TVT, and others, like TVT-Abbrevio – all devices which use mesh containing the same PROLENE* material. When asked whether his Report focuses on TVT, Dr. Karram testified that it does not and that “it’s focused on synthetic slings used for stress incontinence.” Karram Depo. at 82:18-83:10. Furthermore, in his own clinical experience, on

which he also bases his opinions, Dr. Karram estimates that of the sling surgeries he has performed, around 65-70% were transobturator slings (TVT-O). *Id.* at 56:20-57:1.

Plaintiffs suggest that Dr. Karram's opinions on TVT-O are unreliable because just two of the "dozens of papers" he cites in his Report include study of the TVT-O device. But this does not make his opinions about TVT-O inadmissible, as this Court has determined when assessing a similar argument in *Trevino v. Boston Scientific Corp.*, No. 2:13-cv-01617, 2016 WL 1718836 (S.D. W. Va. Apr. 28, 2016). There this Court addressed the argument that an expert's opinions were "not tied to the facts of this case because he only reviewed one scientific article that specifically addresses the [device at issue]." *Id.* at *7. Rejecting the proponent's argument that this warranted exclusion of the expert's opinion, this Court held that "if there are certain device-specific publications that [the expert] failed to review in preparing his expert report, [the opposing party] is free to inquire about those publications on cross-examination." *Id.*

Plaintiffs' argument also fails to take into account the reliability and importance of the TVT-O-related literature that Dr. Karram did review. Dr. Karram's Report cites to both the Trial of Mid-Urethral Slings (TOMUS) study and the Cochrane Library meta-analysis. Expert Report at 21. The TOMUS study is the "largest randomized controlled study comparing retropubic and transobturator slings," and the Cochrane analysis is a high-level meta-analysis of the data from 62 studies. *Id.* Both of these are examples of Level 1 data, showing that Dr. Karram relied on the highest-level analysis available to him. Plaintiffs' argument focuses on the quantity of what Dr. Karram reviewed, while completely ignoring the quality. Plaintiffs' objections to the specific data reviewed, or alleged lack thereof, is not a question of admissibility, but weight of evidence.

As a practicing surgeon, Dr. Karram consistently reviews medical data and literature published on procedures and findings relevant to his field. Plaintiffs argue that Dr. Karram's

opinions fail to account for contrary literature and should be excluded. In so arguing, Plaintiffs fail to identify which of Dr. Karram's opinions ignore contrary evidence or what that alleged contrary evidence is. Similarly, when asked whether he cited any reports or papers that did not support his opinion, Dr. Karram was not provided any opportunity to state his reasons for excluding contradictory evidence, or asked about any specific study or literature which Plaintiffs claim contradicts his opinions. Without more specificity, Plaintiffs are merely throwing everything against a wall to see what sticks.

Finally, Plaintiffs attempt to discredit Dr. Karram by suggesting that data discussed in his Report is incorrect. This baseless suggestion mischaracterizes the evidence, as a discussion of these alleged inaccuracies shows. First, Plaintiffs allege that Dr. Karram's Report lists a failure rate of 3% rather than 9%. Importantly, this error was not in the body of the Report, but in the slides incorporated into Dr. Karram's report. In his deposition, Dr. Karram clarified that he did not author the slides, but they were slides created by another surgeon that he has used in the past. Karram Depo. at 22:14-18. In any event, it is clear that the error is merely a typographical error, one which was made by another individual. The study on which the slide was based reported a failure in 3 cases, which was 9%. *Id.* at 109:5-15. Plainly the failure rate was inadvertently reported as 3% instead of 3 cases on the slide.

Plaintiffs also complain that on another slide, which reports data from 5 studies, the percentages for the three categories, "dry," "improved," and "failed," did not add up to 100%. *See* Pltfs' Memo. at 9-10. Dr. Karram agreed that the three percentages reported added up to 110% rather than 100%, and explained that this may not be an error if there is overlap in the categories. Karram Depo. 106:12-22. Plaintiffs fail to show how this is relevant, in any event, particularly because none of the 5 studies included on the slide have numbers totaling 100%.

The first four total 50%, 51%, 85%, and 94% respectively (Expert Report at 25), though Plaintiffs only take issue with the final Olson study.

A third example is similarly irrelevant. Plaintiffs point to an alleged error in a slide representing data created by someone other Dr. Karram. Pltfs' Memo. at 10. As Dr. Karram clarified in his deposition, this did not lead to any inaccuracies in his understanding of the underlying data. *Id.* at 26; Karram Depo. at 11:8-21. As such, this error, if indeed it was an error, had no effect on the reliability of Dr. Karram's opinions.

III. Dr. Karram's failure to review all potential documents does not undercut the reliability of his testimony based on what he did review.

Despite Plaintiffs' argument to the contrary, any alleged failure by Dr. Karram to review certain documents does not, by itself, change the nature and sufficiency of the documents he did review. In noting that Dr. Karram's updated reliance list removed documents he had not reviewed, Plaintiffs fail to address at all the documents remaining on the list. As previously discussed, Dr. Karram reviewed Level 1 data including the TOMUS study and Cochrane analysis. Expert Report at 21; Karram Depo. at 95:13-96:2. Dr. Karram also reviewed textbooks, journals in the field, abstracts he reviews in the general course of his practice, and other medical literature. Karram Depo. at 94:15-7. Dr. Karram's decision to base his opinions solely on the literature he encountered through his own research and practice and not the documents provided to him in the course of this litigation, such as internal company documents, strengthens the fact that his opinions are based on his own independent analysis. At best, Plaintiffs have raised an issue regarding the credibility and weight of Dr. Karram's testimony, but this argument does not go to the admissibility of his opinions. *See Daubert*, 509 U.S. at 596.

IV. Dr. Karram's opinions are based on more than personal opinion and are admissible.

Contrary to Plaintiffs' argument at 12-15 of their Motion, Dr. Karram has ample broad, general experience that wholly qualifies him to testify about training, warnings, and physician knowledge. Of course Dr. Karram's opinions regarding training are based on his participation in the program – but they are based not only on his participation as a trainee, but also upon the fact that Dr. Karram served as lead faculty on many TVT device training sessions. Expert Report at 26. Through this process, he became extremely familiar with the training processes, materials, procedures, and risks and benefits of the procedures. *Id.* He is fully acquainted with the process of surveying and identifying potential surgeons for training, the information and data provided to the surgeons to review prior to training, the content and techniques used during training sessions, and the certification process. *Id.* at 27. He also is aware of resources provided to surgeons following training, including the ability to use a preceptor to observe their first few procedures performed, a role in which he himself served. *Id.* Dr. Karram's opinions are based not only on his own training experience but also his extensive involvement with the process from start to finish. His intimate knowledge of this process gives him ample basis for opining on the training.

Plaintiffs also argue that Dr. Karram cannot testify to general knowledge of pelvic floor surgeons because he has not talked to each individual one. This statement is simply unreasonable. Dr. Karram has been active in the care of SUI patients for his entire career. *Id.* at 4. His opinions on the knowledge of pelvic surgeons are informed by his experience working with and training “a vast number of pelvic surgeons.” Karram Depo. at 114:3-6. Through his review of medical literature, interaction with others in his field, participation in the education and training of other surgeons, and active participation in professional associations, Dr. Karram is well equipped to opine on the general knowledge of practitioners in his field. He is not merely assuming others have the same knowledge as he does, but is aware of the literature, training, and

educational requirements available to and imposed on his peers and informing them. His testimony is admissible as it is wholly grounded on his knowledge, education, experience, and training as an urogynecologist. Again, to the extent Plaintiffs disagree with Dr. Karram's conclusions, they can raise this issue on cross-examination.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court deny Plaintiffs' motion to exclude the testimony of Dr. Karram regarding the safety and efficacy of the TVT-O product.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on this date, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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